3/19/99



K990189

## 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

(A)(1) Submitter's name: Hamilton Thorne Research
Submitter's address: 100 Cummings Center, Suite 102-C
Beverly, MA 01915
Submitter's telephone no.: 978 -921-2050
Contact Person: Diarmaid Douglas-Hamilton

Date Summary Prepared: January 8, 1999

(2) Trade or proprietary device name: Automarqer™
Common or usual name: Differential spectrophotometer
Classification name: Hematology

(3) Legally marketed predicate device: IVOS sperm analysis system [Hamilton Thorne Research (K920719, SE 6/29/92)].

(4) Subject device description:

The Automarqer™ is a differential spectrophotometer for quantification of results using MARQ™ Test Kits * for sperm analysis. The MARQ test kits employ a unique test cassette with four wells, each containing a filter to retain the test reagents and sample suspension. The test cassette is designed to be inserted into the Automarqer for reading of results after the sample has been processed. The Automarqer provides the numeric analysis of the quantity of sperm or other sperm ejaculate component being evaluated.

The Automarqer operates by measuring the well reflectivity in two wavelengths (red and green) and deriving the optical absorption in DNA-specific dyes within the wells, generated by the staining reagents used in the MARQ test kits. Each well emits a signal in the color with which it is illuminated (either red or blue dye). The first well of the test cassette provides a standard signal (using a standardized latex bead suspension), the second well provides a null signal, and the third and fourth wells provide sample signals.

The Automarqer contains an optical assembly, microprocessor and program, cassette position sensor and readout screen. Software in the microprocessor ROM directs the operations. The microprocessor detects position of the cassette as each well is inserted, stores the value of the signal from each well separately under red and green wavelength illuminations, and computes the corresponding reflectivity of the sample, using the scale defined by the difference between the first two wells (the standard signal and the null signal). In this way, the system is self-calibrating on each cassette.

* *MARQ™ Test Kits are being developed for commercialization by Embryotech Laboratories, Wilmington, MA.*

(5) Subject device intended use:

The Automarqer™ is a differential spectrophotometer for quantification of results using Ferto;MARQ™ Test Kit for sperm concentration analysis.

(6) Performance data:

Equivalent results are obtained on semen samples analyzed by both the Automarqer™ and the IVOS sperm analysis system. Only slight variability has been observed due to the instrument and test cassette design themselves, or to the bead suspension used in the test well for self-calibration. The precision and repeatability of the Automarqer in application is very good, with most of the observed error in the studies coming from the differences in the sample and its administration in the test.

Coefficients of Variation due to equipment (Automarqer, cassette) and sample

| | |
|---|---|
| Automarqer well variability | < 0.15% |
| Cassette well variability | 1.1% |
| Sample well variability | 2.4% |
| simulated sample variability | 20% |
| actual sample variability | 16% |

35 clinical samples obtained for analysis of sperm concentration by both the Automarqer and the IVOS show high degree of correlation, r = 0.997, and samples run by three different operators on 11 samples also showed reproducibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 19 1999

Ms. Diarmaid Douglas-Hamilton
Vice President of Research and Development
Hamilton Thorne Research
100 Cummings Center, Suite 102C
Beverly, Massachusetts 01915-6101

Re: K990184
Trade Name: Automarqer™
Regulatory Class: II
Product Code: MNA
Dated: January 8, 1999
Received: January 20, 1999

Dear Ms. Douglas- Hamilton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## C. Indications for use of the Device



510(k) Number): ~~Not known~~ K990184

Device Name: Automarqer™

Indications for Use:

The Automarqer™ is a differential spectrophotometer for quantification of results using MARQ™ Test Kits for sperm analysis.

***(Please do not write below this line—continue on another page if needed)***

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Peter E Maderi

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

**Prescription Use X Or Over-the-Counter Use**
**(Per 21 CFR 801.109)** (Optional Format 1-2-96)